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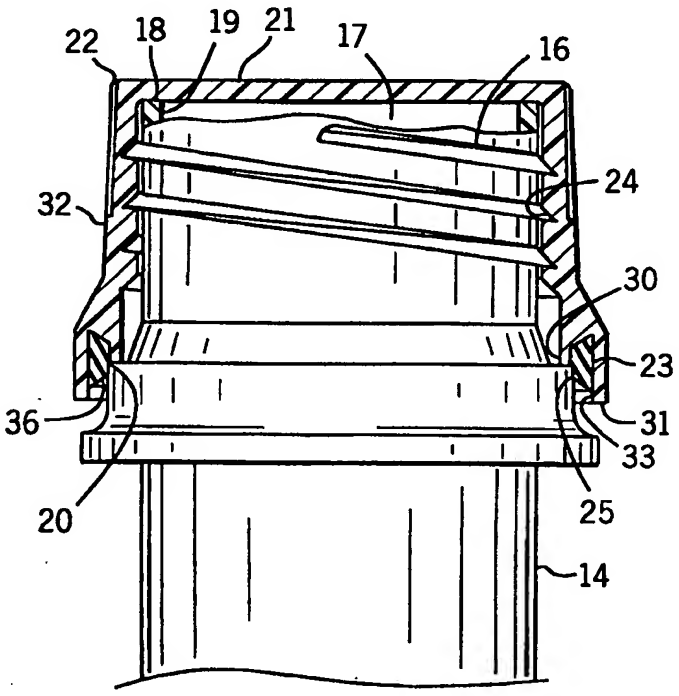
(54) Title: CLOSURE SYSTEM FOR CONTAINERS

(57) Abstract

A closure system (10) for molded plastic containers (12) having a threaded container neck (14), the closure system comprising a screw cap (22) having internal threading (24) constructed for threaded engagement with the threaded container neck, a gasket (36), means (33) for retaining the gasket on the screw cap and an abutment surface (20) integrally formed in and extending substantially radially from the container neck for sealably contacting the gasket, wherein the screw cap and the abutment surface are constructed so that downward axial rotation of the screw cap is effective to seal the gasket against the abutment surface.



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CLOSURE SYSTEM FOR CONTAINERS

Field Of The Invention

The present invention relates, in general, to closure systems for molded plastic containers. In particular, the present invention relates to closure systems for molded plastic containers containing sterile fluids and having a cap associated therewith.

Background Of The Invention

Various food, medical and household products are presently packaged in molded plastic containers. Most of these containers include a dispensing port, and a closure system which creates a barrier for containing and/or protecting the contents of the container until the contents are to be used. Presently, many of these closure systems employ caps which are adapted to be easily removed. In particular, molded plastic containers are used to dispense sterile medical fluids for use in various medical procedures. For example, intravenous solution containers are used to administer parenteral solutions to a patient. Other medical containers are used to dispense irrigating fluids to a surgical site. Still other medical containers are used in enteral nutrition, inhalation, nebulizer, orthoscopic, mirror defogging, and x-ray preparation applications.

These medical containers have a common purpose of maintaining the sterility of their contents during manufacture, shipping, storage and dispensing. A critical portion of these containers is the closure system. The closure system must form and maintain a sterile barrier at a cap/container interface. This sterile barrier must remain intact from the time it is established until the time the container is intentionally opened for use. At the same time, these containers must be easily opened so that the contents of the container may be dispensed at the time of use.

The manufacture of medical containers typically includes a sterilization process such as autoclaving which subjects the container and contents to high temperatures typically in the range of approximately 118-121 degrees C. These temperatures can cause the pressure inside the container to be elevated above the pressure existing outside the container. Also, as the container is being cooled down from sterilizing temperatures, the pressure inside the container may drop below the pressure existing outside the container. The sterile barrier must be capable of withstanding these pressure differentials, to prevent air from any non-sterile environment which may exist outside the container from being drawn into the container during these processes, in order to maintain the sterile barrier.

As the contents of a container are being dispensed, the contents may come into contact with portions of the exterior of the container, therefore, it is often desirable that these areas also remain sterile. For this reason, the sterile barrier is typically located such that an exterior portion of the container adjacent to the dispensing port, including any threadings on the exterior of the container neck, is positioned between the sterile barrier and the contents of the container. In this way, the sterility of an external portion of the container can be maintained.

One means of providing a sterile barrier at a cap/container interface is to place a resilient gasket between the cap and the container and to exert compressive forces to sandwich together the cap, gasket and container whereby a sterile barrier may be established. Nevertheless, continuing problems remain in such closure systems in preventing the breach of the sterile barrier. Inherent factors can create difficulties in the establishment, maintenance and reliability of the sterile barrier. For example, typically the gasket is a separate component of the closure system, which requires that two critical sterile barriers be established and maintained; one at a cap/gasket interface and a second at a gasket/container interface. The reliability of such closure systems, which are dependent on the maintenance of two critical sterile barriers, is lessened as both sterile barriers are subject to failure. Also, such closure systems typically are not constructed to

minimize movement and/or expansion of a gasket in directions other than the directions of applied compressive forces. This can affect the integrity and the reliability of such a closure system. Also, dimensional variations due to molding tolerances of cap, container and gasket components can make such closure systems unreliable and prone to failure.

Therefore, it is desirable to provide a closure system which forms a sterile barrier having high integrity and operational reliability. It is desirable that the sterile barrier be located so that an external area adjacent to the dispensing port remains sterile. It is also desirable to provide a closure system which allows the container to be easily opened so that. the contents of the container may be dispensed at the time of use. Furthermore, since closure systems are often used only once and are disposed of after use, it is desirable that the cost of manufacturing the closure system is relatively low.

Summary Of The Invention

In accordance with the present invention there is provided a closure system for molded plastic containers which is capable of providing a sterile barrier or seal having high integrity and operational reliability. Also, the present invention provides a sterile barrier which is located so that the sterility of an external area adjacent to the dispensing port can be maintained in a sterile condition. Also, the present invention provides a closure system which allows the container to be easily opened at the time of use and which can be manufactured economically.

Specifically, the closure system comprises a screw cap having internal threading constructed for engagement with threading located on the exterior of the container neck. The cap has a sidewall. Inner and outer annular rims are integrally formed and extend downwardly from the sidewall of the cap. A resilient compressible gasket is positioned between the annular rims. The gasket is designed to engage against an abutment surface integrally formed in and extending radially from the container neck, to establish a sterile barrier when the cap is rotated downwardly onto the container neck.

In a preferred embodiment, the gasket and cap are integrally formed in a single injection molding operation to create a unitary component. Also, the abutment surface is subjected to an ultrasonic treatment, called swaging, which smooths the molding seams created during the molding process, particularly along the points-of-contact made by the gasket with the abutment surface when the gasket is fully seated against the abutment surface.

Thus, in accordance with the present invention, a closure system is provided which forms a sterile barrier having high integrity and operational reliability, is easily opened at the time of use, and has a relatively low manufacturing cost.

Numerous other advantages and features of the present invention will become readily apparent from the following detailed description of the invention and the disclosed embodiments thereof, from the claims and from the accompanying drawings in which the details of the invention are fully and completely disclosed as part of this specification.

Brief Description Of The Drawings

FIG. 1 is a side elevation view of the closure system of the present invention;

FIG. 2 is a side elevation view, partially broken away, showing in particular an upper portion of the closure system of the present invention;

FIG. 3 is a cross sectional, side elevation view of a portion of the closure system of the present invention, showing in particular a plug seal;

FIG. 4 is a cross sectional, side elevation view of a portion of the closure system of the present invention, showing in particular a knife seal;

FIG. 4a is an enlarged view of a portion of the closure system of the present invention, showing in particular the gasket area; and

FIG. 5 is a side elevation view of a portion of the closure system of a present invention, showing in particular a knurled cap.

Description Of Preferred Embodiments

While this invention is susceptible of embodiment in many different forms, there is shown in the drawings and will be described herein in detail specific embodiments thereof with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the specific embodiments illustrated.

The closure system incorporating the present invention is typically used with medical administration systems having certain conventional components the details of which, although not fully illustrated or described, will be apparent to those having skill in the art and having an understanding of the necessary functions of such components.

Referring to FIGS. 1 and 2, closure system 10 generally comprises molded plastic container 12 including container shoulder 13. Container 12 includes container neck 14 extending upwardly from container shoulder 13. Container 12 has dispensing port 17 defined by pour lip surface 18 formed at container neck 14. Helical external threading 16 is located on container neck 14. Abutment surface 20 is integrally formed on, and extends substantially radially from, container neck 14 and is located between external threading 16 and container shoulder 13. Closure system 10 further comprises screw cap 22 having helical internal threading 24 of proper size and construction for rotatable engagement with external threading 16 on container neck 14.

Screw cap 22 includes top wall 21 and continuous cylindrical sidewall 32 extending downwardly from top wall 21. Inner annular rim 30 and outer annular rim 31 are integrally formed on, and extend downwardly from, sidewall 32 of screw cap 22. Inner annular rim 30 has a diameter which is less than the diameter of outer annular rim 31. Annular recess 33 is defined by inner and outer annular rims 30 and 31. Closure system 10 further comprises gasket 36 which is retained on screw cap 22. Gasket 36 may be retained on screw cap 22 by being positioned in annular recess 33 and held there by being pressure-fitted into place. Alternatively, gasket 36 may be retained on screw cap 22 other means, such as by being molded-in-place.

Container 12 may be manufactured by conventional molding procedures using a thermoplastic material such as polypropylene, polyvinylchloride, polyethylene terphthalate, butadiene styrene, acrylics including acrylonitrile, polytetrafluoroethylene, polycarbonates and other thermoplastics. Screw cap 22 may be manufactured by injection molding a thermoplastic material such as polypropylene, polyvinylchloride, polyethylene terphthalate, butadiene styrene, acrylics including acrylonitrile, polytetrafluoroethylene, polycarbonates and other thermoplastics. Gasket 36 may be fabricated from resilient compressible material such as rubber, butadiene, polytetrafluoroethylene (such as TEFLON®, or injectable thermoplastic elastomeric co-polymers (such as KRATON ® or C-FLEX ®). The materials used for the container 12, screw cap 22 and gasket 36 should be selected from among materials compatible with the contents of the container, to prevent the materials from causing chemical changes to the contents of the container during storage and, also, to prevent the contents of the container from causing physical or chemical changes to the materials.

In a preferred embodiment as shown in FIG. 3, plug seal 40 extends downwardly from top wall 21 and coaxially with sidewall 32, with plug seal 40 having a diameter which is less than the diameter of sidewall 32. Plug seal 40 is configured to contact interior surface 19 of container neck 14. Plug seal 40 functions to create a barrier to reduce the likelihood of contact between the contents of container 12 and an exterior

portion of container 12 adjacent to dispensing port 17, including external threading 16, prior to the time the contents of container 12 are used. This contact might otherwise occur, for example, as a result of splashing caused by the handling of container 12 during shipping or storage. Plug seal 40 is constructed so that contact between plug seal 40 and interior surface 19 does not prevent engagement of gasket 36 with abutment surface 20 upon engagement of internal threading 24 in screw cap 22 with external threading 16 on container neck 14. Also, abutment surface 20, screw cap 22 and gasket 36 are constructed so that contact between gasket 36 and abutment surface 20 does not prevent a barrier from being created by plug seal 40 coming into contact with interior surface 19, upon engagement of internal threading 24 in screw cap 22 with external threading 16 on container neck 14.

In an alternate preferred embodiment, knife seal 50 is extended downwardly from top wall 21 and coaxially with sidewall 32, with knife seal 50 having a diameter which is less than the diameter of sidewall 32. Knife seal 50 is configured to contact pour lip surface 18. Knife seal 50 functions to create a barrier to reduce the likelihood of contact between the contents of container 12 and an exterior portion of container 12 adjacent to dispensing port 17, including external threading 16, prior to the time the contents of container 12 are used. Knife seal 50 is constructed so that contact between knife seal 50 and pour lip surface 18 does not prevent engagement of gasket 36 with abutment surface 20 upon engagement of internal threading 24 in screw cap 22 with external threading 16 on container neck 14. Also, abutment surface 20, screw cap 22 and gasket 36 are constructed so that contact between gasket 36 and abutment surface 20 does not prevent a barrier from being created by knife seal 50 coming into contact with pour lip surface 18, upon engagement of internal threading 24 in screw cap 22 with external threading 16 on container neck 14.

External threading 16 and internal threading 24 are constructed to establish sufficient contact between external and internal threadings 16 and 24 to establish a sterile barrier or seal at gasket/container interface 25, located between gasket

36 and abutment surface 20, and to maintain the sterile barrier from the time sterilization is established until the time the contents of container 12 are to be used.

In a preferred embodiment, container 12 is extrusion blow molded and is then subjected, to a well-known treatment, namely ultrasonic treatment (sometimes referred to as swaging), which smooths the molding seams created during the molding process, particularly along the points-of-contact made between gasket 36 and abutment surface 20 when gasket 36 is fully seated against abutment surface 20.

In a preferred embodiment of the present invention, container 12 and screw cap 22 are polypropylene and gasket 36 is polytetrafluoroethylene. Also, screw cap 22 and gasket 36 are molded simultaneously using a well-known technique. One such technique is a molding process know as two-shot injection molding. The use of a two-shot injection molding process causes screw cap 22 and gasket 36 to bond together thereby producing a unitary component. In a preferred embodiment, screw cap 22, (including inner annular rim 30 and outer annular rim 31 integrally formed on sidewall 32 of screw cap 22) is produced by injection molding. Next, gasket material is injected as a "second shot" and gasket 36 is molded between inner and outer annular rims 30 and 31. In an alternate embodiment, gasket 36 is produced by injection molding. Next, screw cap material is injected as a "second shot" and screw cap 22 is molded onto gasket 36.

Using two-shot injection molding to form gasket 36 and screw cap 22 can reduce the overall cost of the parts because the costs of handling, shipping, and stocking individual ly-molded gasket 36 and screw cap 22 parts may be avoided. Also, the cost of customized equipment which may otherwise be required to subsequently sort and assemble individually-molded gasket 36 and screw cap 22 parts may be avoided. Also, closure system 10 produced using the two-shot process can offer a reduced risk of a breach of sterility at a sterile barrier at cap/gasket interface 23 because the cap/gasket interface 23 is virtually eliminated when the materials used for screw cap 22 and for gasket 36 reflow and bond during the second shot of the process. Screw cap 22 and

gasket 36 are essentially fused together. Also, the two-shot process can produce a closure system 10 in which dimensional variations which would otherwise affect the fit between gasket 36 and screw cap 22, and which would otherwise make the closure system less reliable and more prone to failure, are negated by forming gasket 36 and screw cap 22 into a unitary component.

In a preferred embodiment, container 12, screw cap 22, gasket 36 and the contents of container 12 are assembled and then the assembly is sterilized. Thus, the contents of container 12 are sterilized along with that portion of the assembly which is located on the sterile side of the sterile barrier, including the interior of container 12 and an exterior portion of container 12 (including external threading 16) which may come in contact with the contents of container 12 during use. In an alternate preferred embodiment, screw cap 22, gasket 36 and container 12 are sterilized and then closure system 10 is filled and assembled using aseptic procedures.

To attach screw cap 22 to container 12, screw cap 22 is threadably rotated downwardly on container neck 14, with engagement of internal threading 24 in screw cap 22 with external threading 16 on container neck 14, until further downward movement of screw cap 22 is retarded as compressed resilient gasket 36 comes into resistive contact with abutment surface 20. Inner and outer annular rims 30 and 31 retain gasket 36 and minimize movement and expansion of gasket 36 in directions other than the directions of applied compressive forces. Undesirable movements of gasket 36 are thereby eliminated and closure system 10, having high integrity and operational reliability, is provided.

Screw cap 22 may be removed from container 12 so that the contents of container 12 may be used. Subsequently, screw cap 22 may be reseated onto container neck 14.

Closure system 10 may include heat shrinkable outer member 60 which

is placed external to container 12 to envelop the cap/container interface, thereby providing a tamper evident seal.

FIG. 3 illustrates a preferred embodiment of closure system 10 incorporating the present invention in which a distal end 38 of gasket 36 forms an angle "x" of between approximately 28 and 38 degrees relative to top wall 21 of screw cap 22, which, when brought into compressive contact with abutment surface 20, results in the establishment of compressive forces in both vertical and non-vertical directions. Also, a proximal end 39 of gasket 36 forms an angle "y" of approximately 35 degrees relative to top wall 21 of screw cap 22. These angles can increase the effectiveness of the sterile barrier provided by closure system 10.

In a preferred embodiment, the exterior surface of sidewall 32 contains knurls 70 so screw cap 22 can be removed more easily at the time of use.

From the foregoing, it will be observed that numerous modifications and variations can be effected without departing from the true spirit and scope of the novel concept of the present invention. It will be appreciated that the present disclosure is intended as an exemplification of the invention, and is not intended to limit the invention to the specific embodiment illustrated. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.

WHAT IS CLAIMED IS

1. A closure system for molded plastic containers having a threaded container neck, the closure system comprising:

a screw cap having internal threading constructed for threaded engagement with said threaded container neck;

a gasket;

means for retaining said gasket on said screw cap; and

an abutment surface integrally formed in, and extending substantially radially from, said container neck, for sealably contacting said gasket;

wherein said screw cap and said abutment surface are constructed so that downward axial rotation of said screw cap is effective to seal said gasket against said abutment surface.

2. A closure system in accordance with Claim 1 wherein said screw cap further comprises:

a top wall;

a continuous cylindrical sidewall extending downwardly from said top wall;

an inner annular rim integrally formed in, and extending downwardly from, said sidewall; and

an outer annular rim integrally formed in, and extending downwardly from, said sidewall;

whereby an annular recess is defined by said inner annular rim and said outer annular rim and wherein said means for retaining said gasket on said screw cap comprises said annular recess into which said gasket is pressure-fitted.

3. A closure system in accordance with Claim 1 wherein

said screw cap further comprises:

a top wall;

a continuous cylindrical sidewall extending downwardly from said top wall;

an inner annular rim integrally formed in, and extending downwardly from, said sidewall; and

an outer annular rim integrally formed in; and extending downwardly from, said sidewall;

whereby an annular recess is defined by said inner annular rim and said outer annular rim and wherein said means for retaining said gasket on said screw cap comprises molding-in-place said gasket within said annular recess.

4. A closure system in accordance with Claim 1 wherein said screw cap further comprises:

a top wall;

a continuous cylindrical sidewall extending downwardly from said top wall;

an inner annular rim integrally formed in, and extending downwardly from, said sidewall; and

an outer annular rim integrally formed in, and extending downwardly from, said sidewall:

whereby an annular recess is defined by said inner annular rim and said outer annular rim and wherein said means for retaining said gasket on said screw cap comprises forming said cap, including said inner and said outer annular rims, onto said gasket using a two-shot molding process.

5. A closure system in accordance with Claim 2 wherein said gasket comprises a distal end which forms an angle of approximately 28 to 38 degrees relative to said top wall of said screw cap.

6. A closure system for blow molded containers for sterile liquids, the closure system comprising:

a container neck extending upwardly from the container, said container neck having external threading;

a screw cap having internal threading constructed for threaded engagement with said external threading of said container neck;

an abutment surface, integrally formed in and extending substantially radially from said container neck; and

a gasket positionable between said screw cap and said abutment surface,

wherein said screw cap and said abutment surface are constructed so that downward axial rotation of said screw cap is effective to seal said gasket against said abutment surface.

7. A closure system in accordance with Claim 6, wherein said abutment surface is treated with an ultrasonic process to smooth said abutment surface.

8. A screw cap for molded plastic containers having a threaded container neck, said screw cap comprising:

a top wall;

a continuous cylindrical sidewall extending downwardly from said top wall;

a gasket;

an inner annular rim integrally formed in, and extending downwardly from, said sidewall; and

an outer annular rim integrally formed in, and extending downwardly

from, said sidewall; whereby an annular recess is defined by said inner annular rim and said outer annular rim wherein said gasket is retained so that downward axial rotation of said screw cap onto the threaded container neck of the molded plastic container is effect to seal said gasket against the molded plastic container.

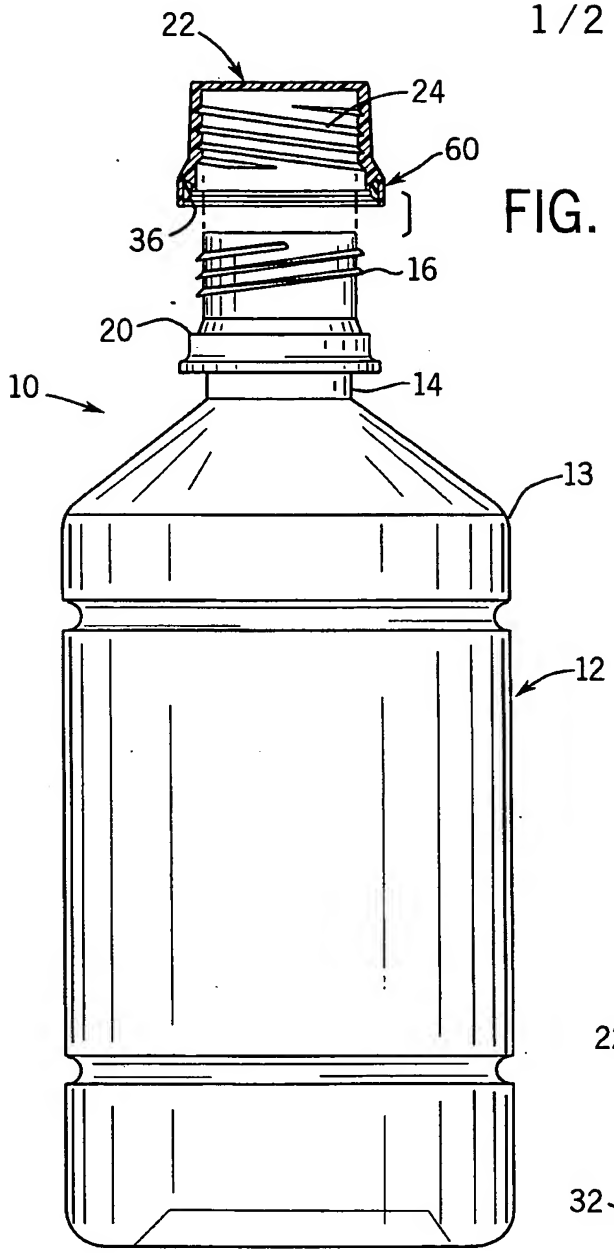
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FIG. 1

FIG. 2

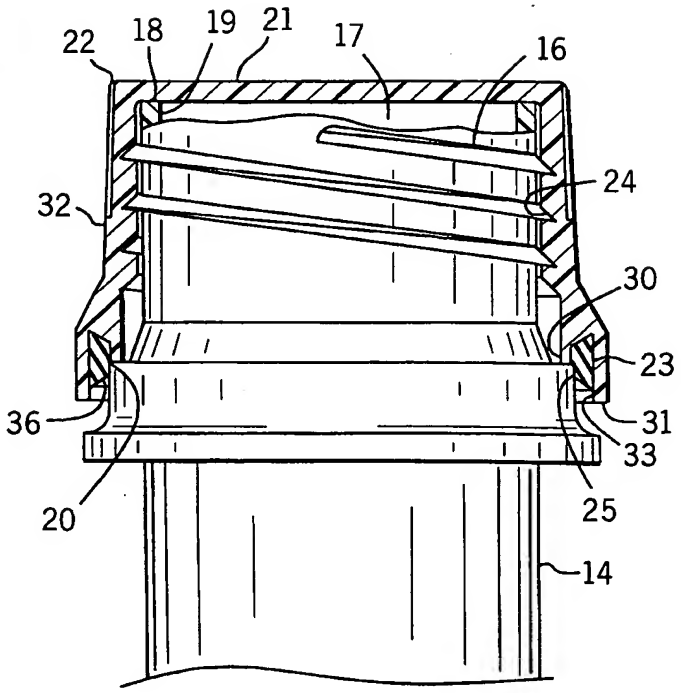
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FIG. 3

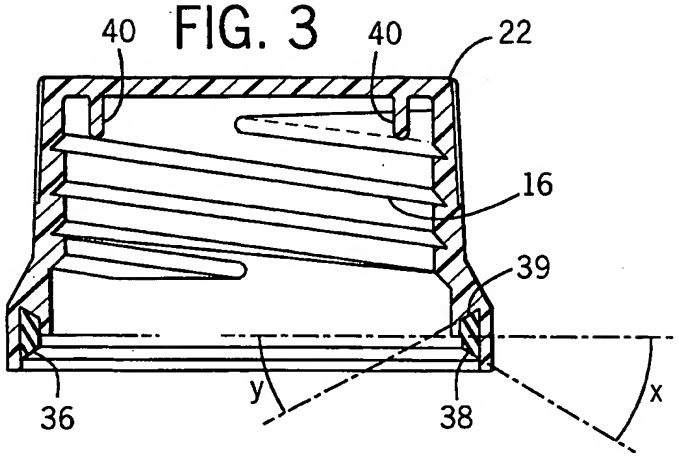


FIG. 4

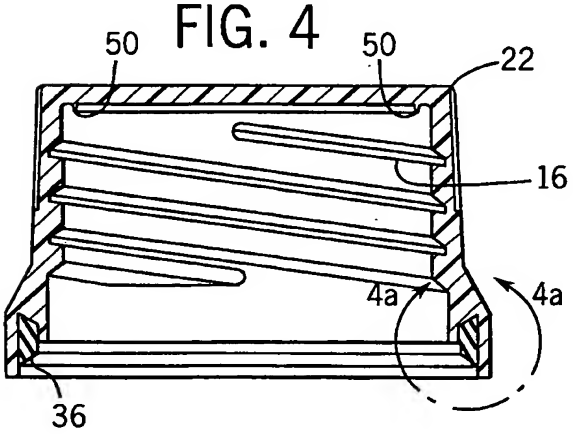


FIG. 4a

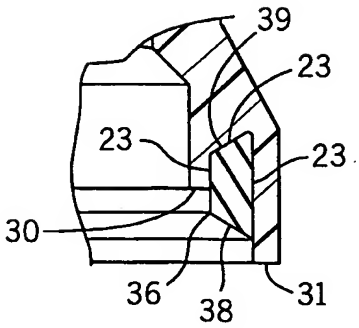
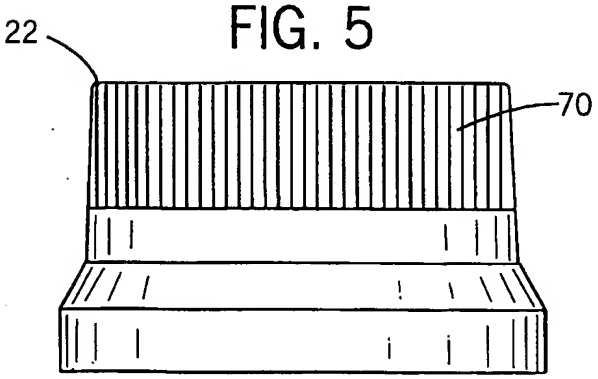


FIG. 5



INTERNATIONAL SEARCH REPORT

Int. ..ional Application No
PCT/US 98/19594

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B65D41/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B65D A61J A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 1 854 451 A (COONEY) 19 April 1932 see page 1, line 66 - page 2, line 10; figures	1,2
X	DE 21 60 798 A (VOLKSWAGENWERK) 14 June 1973 see page 3, paragraph 4 - page 4, paragraph 1; figure	1,2
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Y		6

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Date of the actual completion of the international search	Date of mailing of the international search report
4 January 1999	12/01/1999

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2 022 064 A (BAXTER TRAVENOL LABORATORIES) 12 December 1979 see abstract; figures ---	6
A	GB 2 235 186 A (LAWSON MARDON) 27 February 1991 see page 4, paragraph 3 - paragraph 5; figures -----	3,4

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